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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 520 and 556

Oral Dosage Form New Animal Drugs; Decoquinat

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for adding a dry powder containing decoquinat to whole milk to be fed to calves for prevention of coccidiosis. Also, the regulations are amended to codify an acceptable daily intake (ADI) for decoquinat residues.

**EFFECTIVE DATE:** (*Insert date of publication in the Federal Register.*)

**FOR FURTHER INFORMATION CONTACT:** Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-827-7575.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-060 that provides for adding an 0.8 percent decoquinat medicated powder to whole milk to be fed to ruminating and nonruminating calves including veal calves for prevention of coccidiosis caused by *Eimeria bovis* and *E. zurni*. The NADA is approved as of January 14, 1999, and the regulations are amended by adding 21 CFR 520.534 to reflect the approval.

In addition, FDA is codifying the ADI for decoquinat previously established in Alpharma Inc.'s NADA 39-417 in 21 CFR 556.170.

NFR 1

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.110, a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, **Rockville**, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### **List of Subjects**

#### *21 CFR Part 520*

Animal drugs.

#### *21 CFR Part 556*

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 **CFR** parts 520 and 556 are amended as follows:

### **PART 520— ORAL DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 **CFR** part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

2. Section 520.534 is added to read as follows:

5520.534     **Decoquinat**.

(a) *Specifications.* The drug is a powder containing 0.8 percent **decoquinat**.

(b) *Sponsor.* See No. 046573 in § 51 O.600(C) of this chapter.

(c) *Related tolerances.* See §556.170 of this chapter.

(d) *Conditions of use. Replacement calves—(1) Amount.* Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use.* For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*.

(3) *Limitations.* Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

## **PART 556--TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

3. The authority citation for 21 CFR part 556 continues to read as follows:

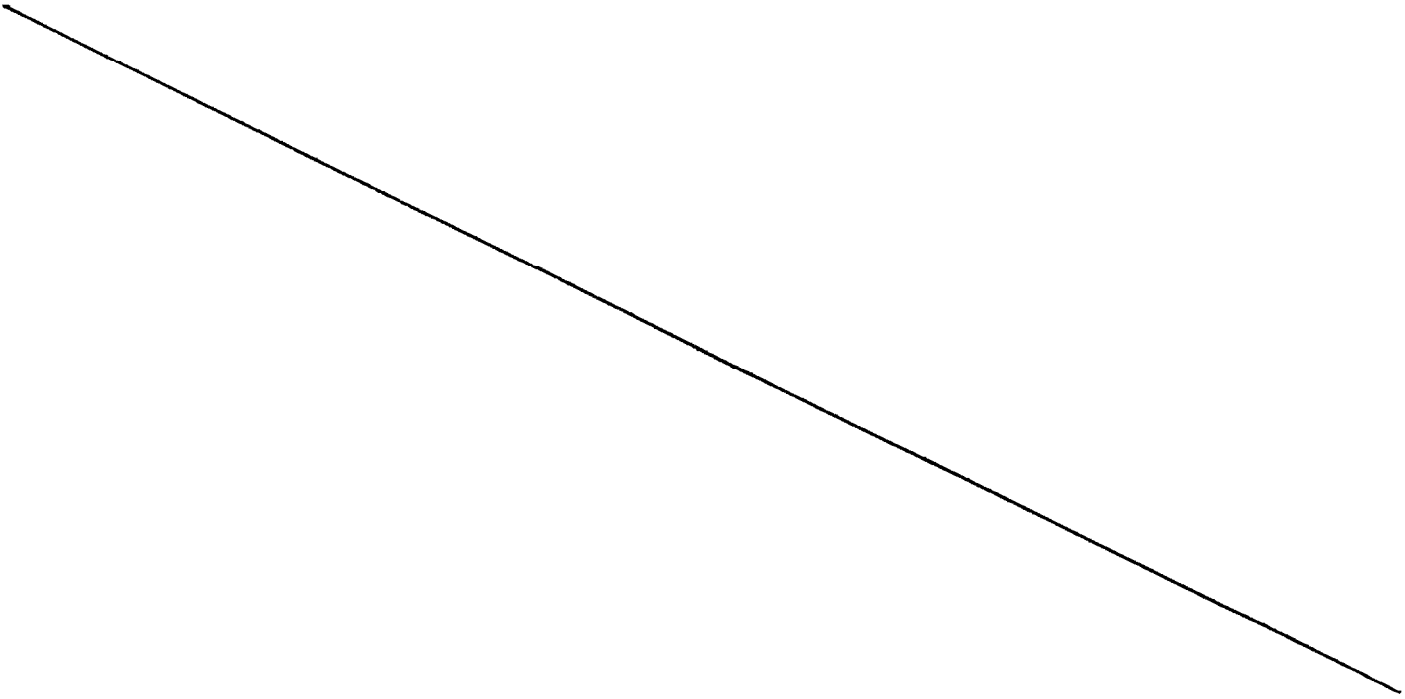
**Authority:** 21 U.S.C. 342, 360b, 371.

4. Section 556.170 is revised to read as follows:

### **§ 556.170     Decoquate.**

(a) *Acceptable daily intake (ADI).* The ADI for total residues of decoquate is 75 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for residues of decoquate in the uncooked, edible

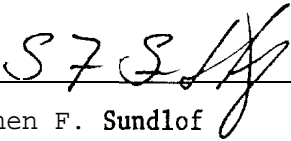


tissues of chickens, cattle, and goats as follows:

(1) 1 part per million (ppm) in skeletal muscle.

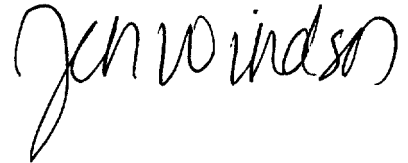
(2) 2 ppm in other tissues.

Dated: 2/19/99  
February 19, 1999



Stephen F. Sundlof  
Director, Center for Veterinary Medicine

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